UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP.,

Plaintiff,

v.

Case No. 2:21-cv-10312

Hon. F. Kay Behm

BLUEWILLOW BIOLOGICS, INC.; ROBIN ROE 1 through 10, gender neutral fictitious names, and; ABC CORPORATION 1 through 10 (fictitious names).

Defendants.

DEFENDANT/COUNTER-PLAINTIFF BLUEWILLOW BIOLOGICS, INC.'S MOTION TO EXCLUDE THE EXPERT REPORT AND TESTIMONY OF AMIRALI Y. HAIDRI

Pursuant to Federal Rule of Evidence 702, controlling law, *Daubert*, and the Court's inherent authority, Defendant/Counter-Plaintiff BlueWillow Biologics, Inc. ("**BlueWillow**"), by and through its undersigned counsel, Foley & Lardner LLP, respectfully moves to exclude the Responsive Expert Report and testimony of Amirali Y. Haidri, Esq. ("**Haidri**") regarding patent invalidity.

On January 17, 2023, BlueWillow's counsel met and conferred with counsel for Plaintiff/Counter-Defendant Trutek Corp. ("**Trutek**"), explained the nature and bases of this Motion, and requested concurrence in the relief sought. Trutek did not concur.

As explained in more detail in the accompanying Brief in Support, the Court must exclude the report and testimony of Haidri as: (1) his report consists entirely of inadmissible legal arguments; (2) Haidri is facially unqualified to provide technical expert testimony regarding the pertinent art, alleged invention, or accused product; and (3) Haidri's opinions lack reference to a verifiable or testable methodology, let alone a sufficiently reliable methodology under *Daubert*.

Dated: March 15, 2023

Respectfully submitted,

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BRIEF IN SUPPORT OF MOTION TO EXCLUDE THE EXPERT REPORT AND TESTIMONY OF AMIRALI Y. HAIDRI

TABLE OF CONTENTS

STATEMENT OF ISSUE PRESENTED iii

TABLE OF AUTHORITIES iv

I. INTRODUCTION 1

II. FACTUAL BACKGROUND 1
- A. Dr. Amiji's Reports (on Behalf of BlueWillow) 3
- B. Haidri's Responsive Report 5
  - 1. Haidri's Purely Legal Arguments 5
  - 2. Haidri's Lack of Qualifications Regarding the Pertinent Art 9

III. LEGAL STANDARD 11

IV. ARGUMENT 13
- A. Haidri's Proposed Testimony Consists of Purely Legal Arguments and is Not Directed to Admissible Subject Matter 13
- B. Haidri is Facially Not Qualified under *Daubert* 17
- C. Haidri Failed to Employ a Reliable Methodology 21
  - 1. Haidri's methodology is not objectively or independently verifiable 21
  - 2. Haidri relied on flawed legal standards and factual predicates 22

V. CONCLUSION 25

STATEMENT OF ISSUE PRESENTED

1. Whether the Court should exclude the expert report and testimony of Amirali Y. Haidri, Esq. as his report consists entirely of inadmissible legal argumentation that would not assist the trier of fact.

BlueWillow's answer: **Yes**.

Trutek's answer: **No**.

2. Whether the Court should exclude the expert report and testimony of Amirali Y. Haidri, Esq. as he does not qualify as an appropriate technical expert regarding the pertinent art, alleged invention, and accused product.

BlueWillow's answer: **Yes**.

Trutek's answer: **No**.

3. Whether the Court should exclude the expert report and testimony of Amirali Y. Haidri, Esq. as his opinions are not based on a verifiable or testable methodology, let alone a sufficiently reliable methodology under *Daubert*.

BlueWillow's answer: **Yes**.

Trutek's answer: **No**.

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Apple, Inc. v. Samsung Electronics Co., Ltd., No. 11-CV-01846, 2012 WL 2571332 (N.D. Cal. June 30, 2012).....22

Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010)..... 24

Bayer Healthcare Pharma., Inv. v. River's Edge Pharma., LLC, No. 1:11-CV-1634, 2015 WL 11122102 (N.D. Ga. Feb. 17, 2015) 21

Berry v. City of Detroit, 25 F.3d 1342 (6th Cir. 1994).....12, 13, 14

Berry v. Crown Equip. Corp., 108 F.Supp.2d 743 (E.D. Mich. 2000)..... 12, 13, 21

Campbell v. AMTRAK, 311 F.Supp.3d 281 (D.D.C. 2018) 25

Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993)..... passim

EEOC v. Kaplan Higher Educ. Corp., 748 F. 3d 749 (6th Cir. 2014) 11

Eiben v. Gorilla Ladder Co., No. 11-CV-10298, 2013 WL 1721677 (E.D. Mich. April 22, 2013) 12

Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d 956 (Fed. Cir. 2002) 5, 24

Federal-Mogul Corp. v. Ins. Co. of Pa., No. 12005, 2016 WL 4486996 (E.D. Mich. Aug. 26, 2016).....23

Ford Motor Co. v. Versata Software, Inc., No. 15-cv-11624, 2018 WL 10733561 (E.D. Mich. July 9, 2018) 23

Hagenbuch v. Sonrai Sys., 130 F.Sup.3d 1213 (N.D. Ill. 2015).....5

In re Lipitor (Atorvastatin Calcium) MKtg. v. Pfizer, Inc., 892 F.3d 624 (4th Cir. 2018) 25

In re SFPP Right-Of-Way Claims, No. CV-15-07492, 2017 WL 2378363 (C.D. Cal. May 23, 2017).....22

Indect USA Corp. v. Park Assist, LLC, No. 18-cv-02409, 2021 WL 4428923 (S.D. Cal. Sept. 24, 2021).....14

Iron Grip Barbell Co., Inc. v. USA Sports, Inc., 392 F.3d 1317 (Fed. Cir. 2005) ..24

Killion v. KeHE Distribs., LLC, 761 F.3d 574 (6th Cir. 2014) 12, 13

Kothmann Enterprises, Inc. v. Trinity Indus., Inc., No. H-01-2668, 2005 WL 8166202 (S.D. Tex. Mar. 29, 2005) 21

KW Plastics v. U.S. Can Co., 131 F.Supp.2d 1289 (M.D. Ala. 2001).....23

Lanard Toys Ltd. v. Anker Play Prods., LLC, No. CV 19-4350, 2020 WL 6783647 (C.D. Cal. Nov. 12, 2020).....15

Malin v. JP Morgan Chase Bank, N.A., No. 3:11-CV-554, 2013 WL 12123511 (E.D. Tenn. May 7, 2013).....19

Mathison v. Boston Sci. Corp., No. 2:13-cv-05851, 2015 WL 2124991 (S.D.W. Va. May 6, 2015) 25

MediaTek Inc. v. Freescale Semiconductor, Inc., No. 11–cv–5341–YGR, 2014 WL 971765 (N.D. Cal. Mar. 5, 2014) 14

Meridia Prods. Liab. Litig. v. Aboot Labs., 447 F.3d 861 (6th Cir. 2006).....19

Mike's Train House, Inc. v. Lionel, L.L.C., 472 F.3d 398 (6th Cir. 2006).....23

Moore v. Ashland Chem., Inc., 151 F.3d 269 (5th Cir. 1998).....22

Okland Oil Co. v. Conoco, Inc., 144 F.3d 1308 (10th Cir. 1998) 16

Prism Techs. LLC v. AT&T Mobility, LLC, No. 8:12CV122, 2014 WL 4705403 (D. Neb. Sept. 22, 2014).....23

Ralston v. Smith & Nephew Richards, Inc., 275 F.3d 965 (10th Cir. 2001).....19

SFG, Inc. v. Musk, No. 19-cv-02198, 2019 WL 8353110 (N.D. Ill. July 31, 2019).....16

Smelser v. Norfolk S. Ry., 105 F.3d 299 (6th Cir. 1997)..... 13, 19, 21

Specht v. Jensen, 853 F.2d 805 (10th Cir. 1988).....13

Sundance, Inc. v. DeMonte Fabricating Ltd., 550 F.3d 1356 (Fed. Cir. 2008)..... passim

Therasense, Inc. v. Becton, Dickinson, 649 F.3d 1276 (Fed. Cir. 2011).....24

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Statutes

35 U.S.C. § 101.....7, 8

35 U.S.C. § 102 ……4

35 U.S.C. § 112.....8, 28

Rules

Federal Rule of Evidence 702..... passim

I. INTRODUCTION

Amirali Y. Haidri, Esq.'s ("**Haidri**") Report and proposed testimony is a textbook example of inadmissible opinion under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). First, his Report consists entirely of legal argumentation that, definitionally, would not assist the trier of fact. Courts have consistently excluded similar backdoor attempts to introduce legal arguments through witness testimony—particularly that of attorneys related to patent invalidity. Second, Haidri does not qualify as an expert having ordinary skill in the relevant art. Indeed, Haidri is a patent attorney who lacks hands-on experience related to pharmaceuticals, nasal sprays, or product development. Third, Haidri's Report does not identify a verifiable or testable methodology, let alone a sufficiently reliable methodology to survive *Daubert*. To the contrary, Haidri's Report consists of legal opinions and self-serving *ipse dixit*. In addition, Haidri relies on fundamentally erroneous legal assumptions and unverified factual predicates. Each of these flaws, independently, require exclusion of Haidri's report and testimony under *Daubert*.

II. FACTUAL BACKGROUND

BlueWillow is a clinical-stage biopharmaceutical company focused on developing intranasal vaccines. (ECF No. 9, Countercl., ¶ 6.) BlueWillow developed and sold NanoBio® Protect ("**NanoBio**"), an over-the-counter nasal

antiseptic that uses BlueWillow's proprietary technology to deliver benzalkonium chloride, a common skin antiseptic that has been used for more than 75 years. (*Id.* ¶ 7.) NanoBio® Protect was discontinued and is no longer sold. (ECF No. 28, Mot. for Leave to File Am. Compl., p. 2; ECF No. 28-1, Kremen Decl., ¶ 7.)

On February 10, 2021, Trutek filed suit alleging one count of infringement of United States Patent No. 8,163,802 ("**'802 Patent**") against BlueWillow with respect to a single product, NanoBio. (ECF No. 1, Compl.). The '802 Patent is attached as Exhibit 6 to the Complaint. (ECF No. 1-6.) Trutek alleges BlueWillow's NanoBio directly infringes "at least claims 1, 2, and 7 of the ['802] Patent because the [NanoBio] products possess an electrostatic charge when applied to a person's nasal passages, and they use benzalkonium chloride as a biocide." (ECF No. 1, Compl., ¶ 30.) Representative claim 1 states:

> 1. A method for ***electrostatically inhibiting harmful particulate*** matter from ***infecting*** an individual through ***nasal inhalation*** wherein a ***formulation*** is ***applied to skin or tissue*** of nasal passages of the individual in a thin film, said method comprising:
>
> a) ***electrostatically attracting*** the particulate matter to the thin film;
>
> b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the ***formulation*** to provide adequate impermeability to the thin film; and,
>
> c) ***inactivating the particulate matter*** by adding at least one ingredient that would render said particulate matter

harmless.

(ECF No. 1-6 (emphasis added).) Representative claim 2 provides:

> 2. A ***formulation*** for ***electrostatically inhibiting harmful particulate*** matter from ***infecting*** an individual through ***nasal inhalation*** wherein the ***formulation*** is ***applied to skin or tissue*** of nasal passages of the individual in a thin film, said formulation comprising at least one ***cationic agent*** and at least one ***biocidic agent***, and wherein said formulation, once applied:
>
> a) ***electrostatically attracts*** the particulate matter to the thin film;
>
> b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the ***formulation*** to provide adequate impermeability to the thin film; and,
>
> c) ***inactivates the particulate matter*** and renders said particulate matter harmless.

(*Id.* (emphases added).)

Without a stretch of the imagination, one would expect that a ***technical*** expert in a case related to the alleged invention and accused product would have relevant technical experience in ***at least*** one or more of the following to be seriously considered as a qualified expert in this matter: (1) electrostatics, (2) pharmaceutical formulation and product development, (3) medicine, (4) infectious diseases, (5) topical drug application, (6) cationic agents, or (7) biocidic agents.

A. Dr. Amiji's Reports (on Behalf of BlueWillow)

BlueWillow submitted three expert reports from Dr. Mansoor M. Amiji, Ph.D. ("**Dr. Amiji**"): (1) Opening Expert Report, (*see* **Ex. 1**), on technical patent

invalidity issues related to (a) anticipation (Section 102) and obviousness (Section 103), (b) subject matter eligibility (Section 101), and (c) utility, written description, and enablement (Section 112); (2) Responsive Expert Report to Edward Lemmo's ("**Lemmo**"), Alexei Ermakov's ("**Ermakov**"), and Shane Burns' ("**Burns**") Reports; and (3) Reply Report to Lemmo's and Haidri's Reports.

Dr. Amiji graduated from Northeastern University with a Bachelor of Science in Pharmacy and is a Registered Pharmacist. (**Ex. 1**, Dr. Amiji Opening Report, ¶ 9.) He has a Ph.D. in Pharmaceutical Science/Pharmaceutics from the School of Pharmacy and Pharmaceutical Sciences at Purdue University. (*Id.*)

Dr. Amiji worked as a Senior Research Scientist for Columbia Research Laboratories in Madison, Wisconsin, where he worked on polymeric delivery systems for various types of therapeutic agents, including those administered topically to skin and mucosal surfaces. (*Id.* ¶ 10.)

Dr. Amiji is a Distinguished Professor, Professor of Pharmaceutical Sciences in the School of Pharmacy, and Professor of Chemical Engineering at Bouve College of Health Sciences at Northeastern University. (*Id.* ¶ 11.) Dr. Amiji has taught and conducted research in pharmaceutical sciences and served as Chairman of the Department of Pharmaceutical Science at Bouve. (*Id.*) Dr. Amiji has ***over 29 years*** of experience in teaching drug formulations to undergraduate and graduate students in the areas of manufacturing and composition of pharmaceutical

formulations, delivery systems, and pharmacokinetics. (*Id.* at 12.) He a consultant to several pharmaceutical, biotechnology, and medical device companies regarding product development and drug delivery. (*Id.*)

Dr. Amiji has published extensively and is ranked as a Thompson-Reuters Highly Cited (top 1%) author in Pharmacology and Toxicology, coauthoring over 60 book chapters and 350 peer reviewed scientific articles. (*Id.* ¶¶ 13–14.)

B. Haidri's Responsive Report

Haidri's Responsive Report to Dr. Amiji's Opening Report on patent invalidity: (a) consists of purely legal arguments, many of which are based on the Manual of Patent Examining Procedure ("**MPEP**"), which is applicable to patent examiners at the U.S. Patent and Trademark Office ("**USPTO**") but not binding on federal U.S. Courts[1]; (b) is not based on any technical expertise in the relevant field(s); and (c) lacks an identifiable or defensible methodology. (*See* **Ex. 2**).

1. Haidri's Purely Legal Arguments

Haidri's Report reads like a legal brief, rather than a technical expert report describing admissible technical opinions on underlying factual issues related to patent invalidity. The content in the introductory sections of Haidri's Report can be summarized as follows:

[1] USPTO guidelines and the MPEP are not binding on courts. *See Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002); *Hagenbuch v. Sonrai Sys.*, 130 F.Sup.3d 1213, 1215 (N.D. Ill. 2015) ("the MPEP is not binding law").

- Section 1 (Terms of Engagement) contains Haidri's engagement letter with Trutek, (*id.* at p. 1);
- Section 2 (Findings and Conclusions) includes seven conclusory findings, all beginning with the legalistic phrase "The Amiji Report did not make a clear and convincing showing . . ." (*id.* at p. 2);
- Section 3 (Relevant Patent Statutes), Section 4 (The Clear and Convincing Standard of Proof), Section 5 (Standards for Inquiry into Patent Invalidity), and Section 6 (Knowledge of the Person of Ordinary Skill) consist entirely of recitations to and legal opinions on statutory interpretation, case law, and legal standards, (*id.* at pp. 3–28); and
- Section 7 (U.S. Patent No. 8,163,802, (The '802 Patent)) is a summary of the text of the asserted patent, (*id.* at pp. 29–38).

In Section 8, where Haidri addresses Dr. Amiji's Opening Report, Haidri advances his views on the legal framework for determining patent invalidity, how the law should be applied to the facts, and Dr. Amiji's (a technical expert) legal prowess. Haidri's legal "opinions" are further misplaced as they are based on inaccurate legal standards, lack citation to legal authority, and/or are applicable only at the U.S. Patent and Trademark Office (i.e., provisions of the MPEP that apply to patent examiners but not courts). For example, in Subsection A, related to ineligible subject matter, in addition to reciting his understanding of the applicable law, Haidri argues:

- "Amiji misinterprets 35 U.S.C. § 101 and is generally unaware of the law and the steps that USPTO patent examiners take to examine for subject matter eligibility," (*id.* p. 42);

- "Under a clear and convincing evidentiary standard, in order to prove invalidity based on ineligible subject matter, the challenger would need to show either that Examiner Henley did not seek to determine whether the claims were directed to eligible subject matter or that no reasonable examiner would have allowed the application to issue as a patent based on the conclusions set forth by Amiji," (*id.*); and

- "the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid for being directed to ineligible subject matter under 35 U.S.C. § 101," (*id.*).

In Subsection B, related to credible utility, Haidri similarly argues:

- "Amiji misunderstands the law," (*id.* at p. 43);

- "There are two aspects relevant to a utility determination. The first is satisfied when a patentee asserts a practical use for his invention," (*id.*);

- "MPEP § 2107 instructs patent examiners as follows . . . Thus, if the inventor asserts that his invention is useful, patent examiners are instructed to rely on that assertion," (*id.*);

- "Rejections under 35 U.S.C. 101 based on lack of credible utility have been sustained by federal courts when . . .," (*id.* at p. 44);

- "Under a clear and convincing evidentiary standard in order to prove invalidity based [on] lack of credible utility, the challenger would need to show either that Examiner Henley did not seek to determine whether the claims had credible utility or that no reasonable examiner would have allowed the application to issue as a patent based on the conclusions put forth by Amiji," (*id.* at p. 45);

- "the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, 7 are invalid for lack of credible utility under 35 U.S.C. § 101," (*id.*).

In Subsection C, related to enablement, Haidri argues:

- "[u]nder the clear and convincing evidentiary standard, the challenger would need to show that no reasonable examiner would have rejected the claims for lack of enablement," (*id.* at p. 49); and

- "the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, 7 are invalid for lack of enablement," (*id.*).

In Subsection D, related to written description, Haidri argues:

- "The written description requirement of 35 U.S.C. § 112(a) is that it must be complete enough as to enable a person of ordinary skill to make and use the invention. It does not need to teach the prior art to those who are unfamiliar with it. It is not necessary to publish results of experiments," (*id.* at p. 51);

- "Thus, the fact finder clearly considered whether the written description requirement of § 112(a) was fulfilled," (*id.*)

- "under a clear and convincing standard, invalidity of the claims for failure to fulfill the written description requirement can be made only if it can be shown that no reasonable examiner would have allowed the claims," (*id.* at p. 52); and

- "the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid for lack of adequate description," (*id.*).

In Subsections E, F, and G, related to anticipation and obviousness, Haidri argues:

- "[b]ecause a clear and convincing showing is required to invalidate a patent, the fact that the examiner considered these two prior art references and allowed the patent application to issue as the '802 Patent should be given great deference," (*id.* at p. 55);

- "the Amiji Report did not make a clear and convincing

showing that claims 1, 2, 6, and 7 are invalid in view of Wahi '488 alone," (*id.*)[2];

- "[b]ecause a clear and convincing showing is required to invalidate a patent, the fact that the examiner considered this prior art reference and allowed the patent application to issue as the '802 Patent should be given great deference," (*id* at p. 76).

In Section 9 (Secondary Consideration - Commercial Success), Haidri recites case law related to secondary considerations and asserts—without factual foundation, technical analysis, or support—that the "commercial success of the NasalGuard® products is due to the products' performance according to the '802 Patent." (*Id.* at p. 78.) In forming his opinion, Haidri relied solely on alleged sales numbers provided orally by Trutek's counsel. (*See* **Ex. 3**, Haidri Dep. Tr., 91:8–93:2.) He also admitted he was merely "told" that Trutek products (i.e., NasalGuard) include ingredients cited in the '802 patent. (*Id*. at 83:20–24.) Haidri also asserts, without factual support, that "[a]ll products sold in the United States [by Trutek] had the '802 Patent number printed on the packaging." (**Ex. 2**, p. 77.)

2. Haidri's Lack of Qualifications Regarding the Pertinent Art

Haidri has a B.S. in Chemical Engineering, Masters in Organic Chemistry, and J.D. (*See id.* at Ex. A.) His only experience even tangentially related to the pertinent art, asserted invention, and accused product arises out of his career as a

[2] Haidri makes the exact same assertions for every item of prior art and combination identified by Dr. Amiji. (**Ex. 2**, pp. 60, 64, 67, 68, 71, 74.)

patent attorney (which is insufficient under binding case law). Aside from being a lawyer, Haidri lacks practical, technical and clinical experience in ***formulating***:

(1) pharmaceutical compositions that are intended to inhibit the nasal inhalation of any environmental particulate matters, (**Ex. 3**, Haidri Dep. Tr., 52:3–8);

(2) pharmaceutical compositions that are intended to capture and hold particulate matter within the human nose, (*id.* at 52:9–14);

(3) pharmaceutical compositions that comprise cationic or anionic agents, (*id.* at 52:15–19);

(4) pharmaceutical compositions that comprise biocidic agents, (*id.* at 53:2–6);

(5) pharmaceutical compositions with biocidic agents for application for nasal administration, (*id.* at 53:7–12);

(6) pharmaceutical compositions that use biocidic agents for the purpose of inhibiting infection by bacteria or viruses, (*id.* at 53:21–54:1); and

(7) pharmaceutical products intended to prevent infection caused by the common cold, (*id.* at 55:1–6).

Haidri lacks practical, technical, and clinical experience in ***testing***:

(1) pharmaceutical compositions to confirm whether they will work for their intended purpose, (*id.* at 54:2–7);

(2) pharmaceutical compositions to determine if they are affective to capture and hold particulate matter within the nose or nasal passage, (*id.* at 54:8–13); and

(3) pharmaceutical compositions to determine if they are effective to inhibit infection by bacteria or viruses, (*id.* at 54:14–19).

In fact, Haidri lacks experience in human clinical testing and product development

altogether. (*Id.* at 56:1–19.) The only presumable basis for arguing Haidri is qualified as a technical expert is that he has a chemistry degree and is a patent attorney—both of which are insufficient under binding precedent.

III. LEGAL STANDARD

As the proponent of expert testimony, Trutek bears the burden of establishing its admissibility. *EEOC v. Kaplan Higher Educ. Corp.*, 748 F. 3d 749, 752 (6th Cir. 2014). Trutek must demonstrate the "validity and reliability of [its expert's] theories." *Berry v. Crown Equip. Corp.*, 108 F.Supp.2d 743, 749 (E.D. Mich. 2000).

Federal Rule of Evidence 702, as explicated in *Daubert*, governs the admissibility of expert testimony. Rule 702 provides:

> A witness who is ***qualified as an expert by knowledge, skill, experience, training, or education*** may testify in the form of an opinion or otherwise if:
>
> > (a) the expert's scientific, technical, or other specialized knowledge will help the ***trier of fact*** to understand the evidence or to ***determine a fact in issue***;
> >
> > (b) the testimony is based on sufficient facts or data;
> >
> > (c) the testimony is the ***product of reliable principles and methods***; and
> >
> > (d) the expert has ***reliably applied the principles and methods*** to the facts of the case.

Fed. R. Evid. 702 (emphasis added).

As a threshold matter, admissible expert testimony must assist the ***trier of***

fact to be admissible. *See id.* The Sixth Circuit has expressly and unequivocally held that "recitation of legal principles . . . is not appropriate expert testimony." *Killion v. KeHE Distribs., LLC*, 761 F.3d 574, 592–93 (6th Cir. 2014). Experts may be qualified "to assist the trier of fact" but are "not qualified to compete with the judge in the function of instructing the jury . . . ." *Berry v. City of Detroit*, 25 F.3d 1342, 1354 (6th Cir. 1994).

Once the subject matter of proposed expert testimony is deemed appropriate, Rule 702 requires courts to ensure that proffered expert testimony is reliable and relevant. *Daubert*, 509 U.S. at 597. "[T]he trial court must determine whether the expert's training and qualifications relate to the subject matter of his proposed testimony." *Berry*, 108 F. Supp.2d at 749. To qualify as an expert under Rule 702, "a witness must first establish his [or her] expertise by reference to his [or her] 'knowledge, skill, experience, training, or education.'" *Eiben v. Gorilla Ladder Co.*, No. 11-CV-10298, 2013 WL 1721677, at *11 (E.D. Mich. April 22, 2013). Specifically for patent invalidity issues (the only issue on which Haidri offers opinions), the Federal Circuit has made clear that an expert must also demonstrate he or she has "skill in the pertinent art." *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1363 (Fed. Cir. 2008) ("We hold that it is an abuse of discretion to permit a witness to testify as an expert on the issues of . . . invalidity unless that witness is qualified as an expert in the pertinent art.").

If the proposed expert "has crossed the foundational threshold of establishing his personal background qualifications as an expert, he must then provide further foundational testimony as to the validity and reliability of his theories." *Berry*, 108 F. Supp. 2d at 749. A methodology cannot be considered reliable unless, at a minimum, it is based on objective criteria and subject to independent validation. *Smelser v. Norfolk S. Ry.*, 105 F.3d 299, 303 (6th Cir. 1997).

IV. ARGUMENT

Trutek cannot meet its burden to establish that: (a) Haidri's proposed testimony is directed to admissible subject matter given that his Report consists entirely of legal argumentation; (b) Haidri is qualified to serve as a technical expert given his lack of experience and qualifications in the pertinent art; and (c) Haidri employed a scientifically testable and verifiable methodology.

A. Haidri's Proposed Testimony Consists of Purely Legal Arguments and is Not Directed to Admissible Subject Matter

Federal Rule of Evidence 702 foundationally requires that, to be admissible, proposed expert testimony must assist the ***trier of fact***. The Sixth Circuit has expressly held that "recitation of legal principles . . . is not appropriate expert testimony." *Killion*, 761 F.3d at 592. Experts may be qualified "to assist the trier of fact" but are "not qualified to compete with the judge in the function of instructing the jury . . . ." *Berry*, 25 F.3d at 1354. "[I]t is axiomatic that the judge is sole arbiter of the law and its applicability." *Specht v. Jensen*, 853 F.2d 805, 807 (10th

Cir. 1988). From both the advisory committee's comments on Federal Rule of Evidence 702 and well established case law, it indisputable that "an expert witness may not give an opinion on ultimate issues of law." *Id.* at 808 (collecting cases) (citing *United States v. Zipkin*, 729 F.2d 384, 387 (6th Cir. 1984)).

However, this is exactly what Haidri's proposed testimony entails—in its entirety. Indeed, Haidri goes well beyond simply stating the legal principles he applied. Rather, his expert report reads like a legal brief, *e.g.*, explaining how patent examiners apply the MPEP and his opinions on what a defendant must prove to demonstrate patent invalidity (often relying on incorrect and/or inapplicable legal standards). He also summarily advances unsupported and conclusory opinions as to underlying factual questions regarding whether the asserted patent is invalid, without having the appropriate technical background or qualifications to do so.

"While expert testimony can be used to provide evidence of the state of the art, how one of ordinary skill in the art would understand the prior art references, and whether one of ordinary skill in the art would have been motivated to combine or modify prior art references in a manner that yields the claimed invention, it is improper to provide testimony that is merely a legal conclusion." *Indect USA Corp. v. Park Assist, LLC*, No. 18-cv-02409, 2021 WL 4428923, at *4 (S.D. Cal. Sept. 24, 2021); *see also MediaTek Inc. v. Freescale Semiconductor, Inc.*, No. 11–

cv–5341–YGR, 2014 WL 971765, at *5 (N.D. Cal. Mar. 5, 2014) (excluding opinion engaging in claim construction and "relying heavily on the prosecution history, specifications, and even provisional applications to explain and expound upon a specific meaning and/or requirements of the terms identified").

Indeed, Haidri's conclusory opinions lack probative technical support and are directed to ultimate legal determinations. For example:

- Section 2 (Findings and Conclusions) includes seven findings all beginning with the legal phrase "The Amiji Report did not make a clear and convincing showing . . ." (**Ex. 2**, p. 2);

- Section 3 (Relevant Patent Statutes), Section 4 (The Clear and Convincing Standard of Proof), Section 5 (Standards for Inquiry into Patent Invalidity), and Section 6 (Knowledge of the Person of Ordinary Skill[3]) consist entirely of recitations to and legal opining on statutory interpretation, case law, and legal standards, (*id.* at pp. 3–28); and

- Section 7 (U.S. Patent No. 8,163,802, (The '802 Patent)) is a summary of the text of the patent at issue, (*id.* at pp. 29–38).

This is definitively not proper subject for expert testimony. *See Lanard Toys Ltd. v. Anker Play Prods., LLC*, No. CV 19-4350, 2020 WL 6783647, at *4 (C.D. Cal. Nov. 12, 2020) ("Delman's opinion on the weight of Gottlieb's testimony is not helpful to the jury. Further, much of the Delman report contains legal conclusions and legal analysis, including a thorough discussion of the case law which is not the

[3] It is unclear how Haidri should be permitted to testify as to the appropriate level of skill in the art when he lacks even the basic level of experience he advocates is required. (*Compare* **Ex. 2**, Haidri Report, pp. 26–27 *with supra* Section II(B)(2).)

proper subject of expert testimony.").

In Section 8, where Haidri addresses Dr. Amiji's Opening Report, Haidri advances a purely legal analysis. Indeed, Haidri repeatedly argues, and ultimately concludes on every issue, that Amiji's Report is not legally sufficient under a clear and convincing evidence standard. *See supra* Section II(B)(1). By way of example, Haidri's analysis in Section VIII(A) (Patent Eligible Subject Matter) provides his opinions on legal standards, a conclusory recitation of what the asserted patent describes,[4] and an ultimate conclusion of law regarding the legal sufficiency of Dr. Amiji's report. (**Ex. 2**, Haidri Report, pp. 39–41). The remaining sections of Haidri's analysis suffers from the same flaws.

Despite assertions to the contrary, "an expert may not state his or her opinion as to legal standards . . . ." *Okland Oil Co. v. Conoco, Inc.*, 144 F.3d 1308, 1328 (10th Cir. 1998). As is the case here, a patent lawyer's expert report (and related testimony) must be excluded when it "read[s] much like trial briefs," "consist[s] of the application of well-established legal standards," and merely renders a legal conclusion based on a summary of perceived facts. *See SFG, Inc. v. Musk*, No. 19-cv-02198, 2019 WL 8353110, at *2 (N.D. Ill. July 31, 2019).

[4] As explained in the following section, Haidri lacks the appropriate qualifications to provide analysis or opinions as to the asserted patent, the prior art, and the issues of invalidity—"each of which are exclusively determined from the perspective of a person of ordinary skill in the art." *Sundance*, 550 F.3d at 1361.

B. Haidri is Facially Not Qualified under *Daubert*

Under binding Federal Circuit case law, an expert must demonstrate he or she has "skill in the pertinent art." *Sundance*, 550 F.3d at 1361, 1363 (excluding patent attorney testimony as the expert "offered expert testimony on several issues that are determined from the perspective of ordinary skill in the art," including "how the disclosed invention and prior art operate, including [] opinions as to [] noninfringement and invalidity," "[d]espite the absence of any suggestion of [] relevant technical expertise"). "Admitting testimony from a person such as [Haidri], with no skill in the pertinent art, serves only to cause mischief and confuse the factfinder. Unless a patent lawyer is also a qualified technical expert, his testimony on [] technical issues is improper and thus inadmissible." *Id.* "Allowing a patent law expert without [] technical expertise to testify on the issues of [] validity amounts to nothing more than advocacy from the witness stand." *Id.* at 1364–65. Indeed, the Federal Circuit has, on "several occasions," upheld the exclusion of testimony by a supposed patent law expert. *Id.* at 1363 (collecting cases). Here, Haidri's lack of technical expertise in the pertinent art is undeniable.

Aside from his work as a patent attorney, Haidri testified that he lacks hands-on experience in ***formulating***:

> (1) pharmaceutical compositions that are intended to inhibit the nasal inhalation of any environmental particulate matters, (**Ex. 3**, Haidri Dep. Tr., 52:3–8);

(2) pharmaceutical compositions that are intended to capture and hold particulate matter within the human nose, (*id.* at 52:9–14));

(3) pharmaceutical compositions that comprise cationic or anionic agents, (*id.* at 52:15–19);

(4) pharmaceutical compositions that comprise biocidic agents, (*id.* at 53:2–6);

(5) pharmaceutical compositions with biocidic agents for application for nasal administration, (*id.* at 53:7–12);

(6) pharmaceutical compositions that use biocidic agents for the purpose of inhibiting infection by bacteria or viruses, (*id.* at 53:21–54:1); and

(7) pharmaceutical products intended to prevent infection caused by the common cold, (*id.* at 55:1–6).

Aside from his work as a patent attorney, Haidri testified that he lacks hands-on experience in ***testing***:

(1) pharmaceutical compositions to confirm whether they will work for their intended purpose, (*id.* at 54:2–7);

(2) pharmaceutical compositions to determine if they are affective to capture and hold particulate matter within the nose or nasal passage, (*id.* at 54:8–13); and

(3) pharmaceutical compositions to determine if they are effective to inhibit infection by bacteria or viruses, (*id.* at 54:14–19).

Indeed, Haidri has ***no*** experience in human clinical testing of pharmaceutical products or developing pharmaceutical products (let alone in the pertinent space). (*Id.* at 56:1–19.) It is not sufficient that Haidri is qualified in *something*; his

qualifications must "provide a foundation for a witness to answer a specific question." *Smelser*, 105 F.3d at 303; *see also Meridia Prods. Liab. Litig. v. Abbot Labs.*, 447 F.3d 861, 868 (6th Cir. 2006). Haidri has "never given lectures, taught any courses, or authored any articles or books on the subjects" related to the alleged invention or accused product. *See Malin v. JP Morgan Chase Bank, N.A.*, No. 3:11-CV-554, 2013 WL 12123511, at *3 (E.D. Tenn. May 7, 2013). In addition, merely possessing a "degree" is not sufficient to permit testimony on any issue within a field. *See Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 970 (10th Cir. 2001) ("merely possessing a medical degree is not sufficient to permit a physician to testify concerning any medical-related issue").

Nor is it sufficient, as Trutek may argue, that a person has related experience in patent prosecution to satisfy *Daubert*. Any technical qualifications that arise solely from a patent attorney's experience in prosecuting patents does not qualify such person to provide testimony on issues of patent validity. Like in *Sundance*, Haidri's only experience in the relevant field comes from prosecuting patent applications. (*See* **Ex. 3**, Haidri Dep Tr., 48:6–24; 50:20–56:19). *Sundance*, 550 F.3d at 1362, n. 4 (excluding expert testimony where the only example of experience "in the [] field" was the result of the expert's experience "in prosecuting patent applications"). Similarly, Haidri makes no mention in his expert report, or his CV, regarding any technical qualifications or practical experience he possesses

in the relevant field.[5] Indeed, both focus exclusively on Haidri's years of experience as a patent lawyer. *Cf. id*. Perhaps more concerning, Haidri does not even satisfy Trutek's lower definition of a person of ordinary skill in the art—i.e., he does not have any experience in making chemical formulations, let alone years of such experience. (**Ex. 2**, Haidri Report, p. 27 ("[T]he minimum requirement for a person of ordinary skill is that he should have adequate experience in making chemical formulations" and further providing an example of a "chemical laboratory technical who has several years experience in making chemical formulations of the type discussed in the patent specification.").) *See also Sundance*, 550 F.3d at 1362, n. 4 (noting expert's definition of person of ordinary skill required "one or more years of experience in the field of tarps or covers—experience that he himself lacks").

"This is a straight forward issue." *Bayer Healthcare Pharma., Inv. v. River's Edge Pharma., LLC*, No. 1:11-CV-1634, 2015 WL 11122102, at *12 (N.D. Ga. Feb. 17, 2015) (quoting *Sundance*, 550 F.3d at 1364) (collecting cases) (excluding patent attorney's testimony in pharmaceutical case). "*Sundance* could not be clearer: patent attorneys are not only prohibited from providing expert testimony on the issues of [] validity, but also from testifying about 'any of the underlying

[5] Notably, apart from a cover letter providing the "terms of engagement" that merely refer to his degrees and licensure as a practicing patent attorney, Haidri's Report provides no explanation of his supposed qualifications. (**Ex. 2**, Haidri Report, p. 1.) Likewise, Haidri's CV details an employment history exclusively related to trademark and patent law. **(Ex. 3**, Haidri Dep. Tr., Ex. A, pp. 45–48).

technical questions, such as the nature of the claimed invention, the scope and content of prior art, the differences between the claimed invention and the prior art, or the motivation of one of ordinary skill in the art to combine these references to achieve the claimed invention.'" *Id.*

C. Haidri Failed to Employ a Reliable Methodology

If a proposed expert "has crossed the foundational threshold of establishing his personal background qualifications as an expert, he must then provide further foundational testimony as to the validity and reliability of his theories." *Berry*, 108 F. Supp. 2d at 749. Haidri's Report is fundamentally flawed as his "methodology": (1) cannot be objectively or independently verified, and (2) relies on insufficient legal bases and factual predicates.

1. Haidri's methodology is not objectively or independently verifiable

A methodology cannot be considered reliable unless, at a minimum, it is based on objective criteria and subject to independent validation. *Smelser*, 105 F.3d at 303; *see also Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 276 (5th Cir. 1998); *United States v. Orr*, 692 F.3d 1079, 1093–94 (10th Cir. 2012) (finding methodology unreliable because it was untested and based on subjective and arbitrary assumptions). Here, Haidri's report does not cite any methodology, let alone a sufficiently reliable methodology. That is dispositive. *See Kothmann Enterprises, Inc. v. Trinity Indus., Inc.*, No. H-01-2668, 2005 WL 8166202, at *3

(S.D. Tex. Mar. 29, 2005) (excluding patent lawyer testimony lacking basis in recognized methodology); *Apple, Inc. v. Samsung Electronics Co., Ltd.*, No. 11-CV-01846, 2012 WL 2571332, at *6 (N.D. Cal. June 30, 2012) (excluding expert testimony lacking citation to source for methodology or peer-reviewed method).

2. Haidri relied on flawed legal standards and factual predicates

In order for expert testimony to be admissible, it must be based on accurate legal standards. *See Ford Motor Co. v. Versata Software, Inc.*, No. 15-cv-11624, 2018 WL 10733561, at *5, 15 (E.D. Mich. July 9, 2018) (collecting cases) (excluding several expert reports). Courts are similarly "obliged to screen expert testimony to ensure it stems from, not just a reliable methodology, ***but also a sufficient factual basis and reliable application of the methodology to the facts***." *KW Plastics v. U.S. Can Co.*, 131 F.Supp.2d 1289, 1292 (M.D. Ala. 2001) (citation omitted). Expert testimony must rely on a valid connection between facts and the relevant legal inquiry. *See Federal-Mogul Corp. v. Ins. Co. of Pa.*, No. 12005, 2016 WL 4486996, *3 (E.D. Mich. Aug. 26, 2016) Haidri, however, improperly relied on erroneous legal standards and factual predicates.

As a prime example of Haidri's flawed legal assumptions, Haidri opines the clear and convincing evidence standard requires proof that ***no reasonable examiner*** would have rejected a claim to establish invalidity. (**Ex. 2**, Haidri Report, pp. 7, 11, 12, 42, 45, 49, 52.) Problematically, the "no reasonable

examiner" standard has only been applied in the limited context of the "materiality" element for inequitable conduct defenses – a defense that is not even raised in this litigation. *Cf. Therasense, Inc. v. Becton, Dickinson*, 649 F.3d 1276, 1288 (Fed. Cir. 2011). And, even then, the Federal Circuit eventually rejected the standard. *See id.*

Similarly, Haidri's repeated reliance on USPTO guidelines and the MPEP is misplaced, as neither are binding on courts. *See Enzo*, 323 F.3d at 964; *Hagenbuch*, 130 F.Sup.3d at 1215. Simply, an examiner's analysis is generally irrelevant to the question of invalidity. *Cf. Iron Grip Barbell Co., Inc. v. USA Sports, Inc*., 392 F.3d 1317, 1323 (Fed. Cir. 2005) ("the grant of a patent does not create a presumption of validity beyond the requirement that the party seeking to invalidate a patent must prove invalidity by clear and convincing evidence").

Nor is it appropriate for a legal expert to speculate about what occurred in the mind of an examiner, such as Haidri's opinion that "the fact finder clearly considered whether the written description requirement of § 112(a) was fulfilled" (**Ex. 2** at 51). *Zimmer Surgical, Inc. v. Stryker Corp.*, 365 F. Supp. 3d 466, 479–80 (D. Del. 2019). In other instances, Haidri applies the wrong version of the patent statute and misstates the law. (*E.g.*, **Ex. 2** at 51 (explaining the "written description requirement of 35 U.S.C. § 112(a) is that it must be complete enough as to enable a person of ordinary skill to make and use the invention").) More specifically,

Section 112(a) is a designation of the AIA version of the statute, whereas the pre-AIA version applies to the '802 patent. Haidri's explanation of the written description requirement is likewise flawed.[6]

As an example of his numerous factually flawed assumptions, Haidri relied on sales summarily provided by Trutek's counsel when concluding (a) Trutek's products were successful solely because of the alleged patented invention, and (b) "[a]ll products sold in the United States [by Trutek] had the '802 Patent number printed on the packaging." (**Ex. 3**, Haidri Dep. Tr., 91:8–93:2; **Ex. 2**, Haidri Report, p. 77.) Haidri, however, offers no independent factual support for these assertions. To the contrary, he admitted he does not know the ingredients in NasalGuard and was merely "told" that Trutek's products include ingredients cited in the '802 patent. (**Ex. 3**, Haidri Dep. Tr., 83:20–84:1.) Courts have consistently excluded testimony predicated on such uncritical acceptance of spoon-fed

[6] Haidri statement of the written description requirement applies to the enablement standard, not written description. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1340 (Fed. Cir. 2010) (en banc) (Section 112, first paragraph "contains a written description requirement separate from enablement"). Written description requires the specification to clearly allow "persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *Id.* at 1351. The "test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.* Moreover, "the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Id.* As such, evidence such as the clinical report that Haidri relies on (attached as Exhibit D to his report) is irrelevant for written description.

information. *See Campbell v. AMTRAK*, 311 F.Supp.3d 281, 301 (D.D.C. 2018); *Mathison v. Boston Sci. Corp.*, No. 2:13-cv-05851, 2015 WL 2124991, at *25 (S.D.W. Va. May 6, 2015); *cf. In re Lipitor (Atorvastatin Calcium) MKtg. v. Pfizer, Inc.*, 892 F.3d 624, 634 (4th Cir. 2018).

V. CONCLUSION

For the reasons stated herein, BlueWillow requests that the Court exclude the Responsive Expert Report and testimony of Haidri in its entirety.

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Respectfully submitted

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CERTIFICATE OF SERVICE

I hereby certify that, on March 15, 2023, I filed the foregoing document and this Certificate of Service with the Court using the ECF system.

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